GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:4386
ANSWERED ON:21.08.2000
COMBINATION OF PARACETAMOL NIMESULIDE
A. KRISHNASWAMY

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the Drug Controller has not approved Paracetamol-Nimesulide combination;

(b) if so, the reasons for not taking any action against those manufacturers who are engaged in manufacturing of such combination without approval;

(c) whether the State Drug Controllers have the powers to approve such drug combinations; and

(d) if so, the action proposed to be taken by the Government against the State Drug Controllers?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (PROF. RITA VERMA)

(a) to (d) The permission for manufacture of Paracetamol-Nemusulide combination was granted by the Drugs Licensing Authority, Maharashtra and not by the Drugs Controller General of India(DCG(I))However, based on the directions from DCG(I), Maharashtra State Licensing Authority had withdrawn the permission granted by them. The Manufacturers went in appeal to the Maharashtra Govt. and stay was granted by the Appellate Authority of Maharashtra. The matter was brought to the notice of Drug Technical Advisory Board which has advised for review of this fixed dose combination through an Expert Committee and the same is in progress.The Govt. of India acting upon the recommendations of DTAB, has issued directions to all State Govts. Under Section 33(P) of the Drugs & Cosmetic Act 1940 to instruct their Drugs Licensing Authorities not to grant licences for manufacture of new formulations without prior approval of DCG(I).